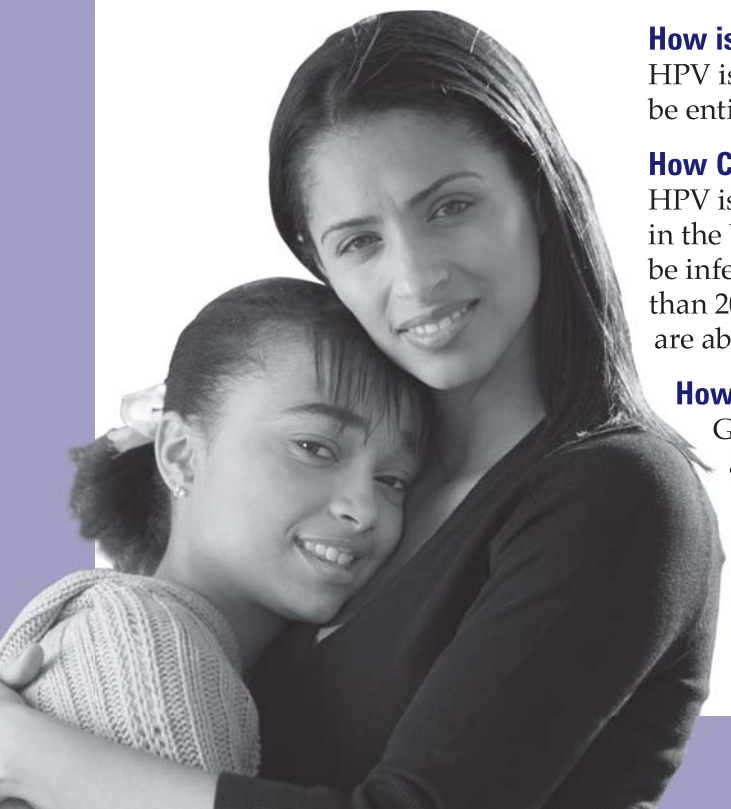
The HPV Vaccine:

What Health Care Providers Need to Know

What are the Main Messages About Human Papillomavirus Vaccine (HPV) for Your Patients?

- Preventing cervical cancer is the most important benefit of HPV vaccine.
- The HPV vaccine includes protection from four HPV types, including two types that cause 70 percent of cervical cancer.
- Three doses of HPV vaccine over six months are needed.
- It is important to receive routine Pap screening for cervical cancer regardless of vaccination against HPV.



Cervical Cancer in the United States: What is the Risk?

Early diagnosis via Pap screening and follow-up treatment has significantly reduced the morbidity and mortality of cervical cancer in the United States. Despite this, in 2007, an estimated 11,150 women will be diagnosed with cervical cancer, and 3,670 women will die from it. More than half of women with cervical cancer have not had a recent Pap test.

What is HPV?

There are more than 100 different types of HPV; over a third of these infect genital epithelial cells (skin and mucous membranes). Genital HPV types are subdivided into high-risk types that can cause cancer and low-risk types that can cause warts. Nearly all cervical cancers are caused by high-risk HPV; types 16 and 18 account for about 70 percent of cervical cancers in the United States and about 40 percent of vulvar and vaginal cancers. Low-risk types 6 and 11 account for about 90 percent of genital warts in men and women. The vast majority of HPV infections are asymptomatic and resolve without ever causing disease.

How is HPV Transmitted?

HPV is transmitted sexually through genital contact and cannot be entirely prevented by condom use.

How Common is HPV Infection?

HPV is among the most common sexually transmitted infections in the United States. Well over half of sexually active people will be infected with genital HPV at some point in their lives. More than 20 million men and women are currently infected, and there are about 6.2 million new infections each year.

How Many HPV Vaccines are There?

Gardasil®, produced by Merck, is a quadrivalent vaccine against HPV types 6, 11, 16, and 18 that is currently licensed for use in females ages 9 to 26. A second vaccine, Cervarix®, developed by GlaxoSmithKline, is a bivalent vaccine against HPV types 16 and 18. Cervarix® has not yet been licensed but is expected to be submitted for review by the Food and Drug Administration (FDA) during 2007.

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visit: www.hpvvaccineca.org

The HPV Vaccine:

How is HPV Vaccine Administered?

The licensed quadrivalent HPV vaccine is given intramuscularly as a 0.5 mL dose in a three-dose series. The second dose is given two months after the first dose. The third dose is given six months after the first dose.

What if a Patient Cannot Complete the Series on Schedule?

If the vaccine series is interrupted, administer the next dose when possible. It is not necessary to restart the series, even if a significant amount of time has passed.

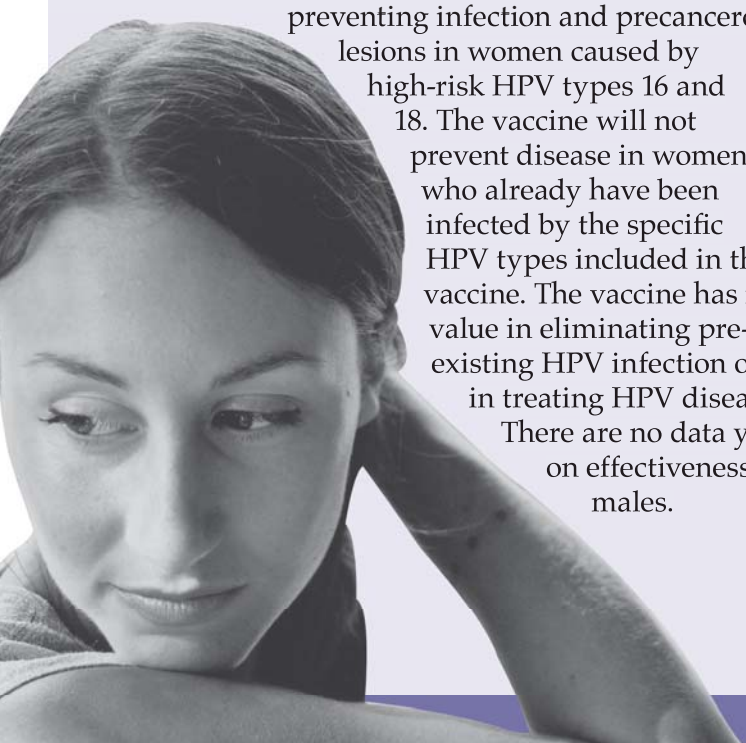
How Safe is HPV Vaccine?

HPV vaccines appear safe. No increase in serious adverse effects have been observed in large clinical trials. The licensed quadrivalent HPV vaccine has been associated with an increase in local injection-site reactions, especially pain.

Continuing studies are monitoring the safety of HPV vaccines. Adverse events occurring after vaccines should be reported to the Vaccine Adverse Event Reporting System (VAERS), which is maintained by the FDA and the Centers for Disease Control and Prevention (CDC). To receive a copy of the vaccine reporting form, call VAERS at (800) 822-7967 or report online at www.vaers.hhs.gov.

How Effective is HPV Vaccine?

In clinical studies, HPV vaccines have been demonstrated to be over 90 percent effective in preventing infection and precancerous lesions in women caused by high-risk HPV types 16 and 18. The vaccine will not prevent disease in women who already have been infected by the specific HPV types included in the vaccine. The vaccine has no value in eliminating pre-existing HPV infection or in treating HPV disease. There are no data yet on effectiveness in males.



How Long Does Immunity Last?

The duration of immunity is not known; current studies have demonstrated protection up to five years. It is not yet known if booster doses will be needed in the future.

For Which Patients is HPV Vaccine Licensed?

Gardasil® is licensed by the FDA for use in females 9 to 26 years of age. The vaccine has not been licensed for use in males.

Who Should Get HPV Vaccine?

The federal Advisory Committee on Immunization Practices (ACIP) recommends three doses of the licensed quadrivalent HPV vaccine for:

- females ages 11 to 12 years on a routine basis, though physicians may vaccinate girls starting at age 9.
- females ages 13 to 26 years, if not yet vaccinated.

Based on current data, females who have not been infected with HPV types included in the HPV vaccine are likely to benefit most from vaccination. Although HPV vaccine can not treat prior HPV infection, sexually active women are unlikely to have been exposed to all HPV types covered by the quadrivalent vaccine. Therefore, sexually active women can still benefit from the vaccine for the virus type(s) in the vaccine they have not yet acquired.

Currently, there are no data on the efficacy of the vaccine in men or women over 26 years of age. Studies in these populations will provide data in the future.

Who Should not be Immunized with HPV Vaccine?

Females who have a history of immediate hypersensitivity (e.g., anaphylaxis) to yeast or to any component of the quadrivalent HPV vaccine should not receive HPV vaccine. Immunization should also be deferred during pregnancy or moderate to severe illness until the illness improves.

What Health Care Providers Need to Know

Should Pregnant Women Receive HPV Vaccine?

The HPV vaccine is not recommended for use during pregnancy. The vaccine has not been associated casually with adverse outcomes of pregnancy or adverse events to the developing fetus; however, data on vaccination during pregnancy are limited. If a woman begins the vaccine series and then becomes pregnant, the series should be suspended until after the pregnancy. No treatment is recommended for women who receive one or more doses of the HPV vaccine while pregnant. Exposures to Gardasil® during pregnancy should be reported to the manufacturer's pregnancy registry at (800) 986-8999 so that the vaccine can be better assessed for safety.

Is HPV Vaccine Required for Entry into Grade School or College?

No. Regardless, providers are encouraged to provide a routine medical visit for children 11 to 12 years old and to urge parents to vaccinate their children according to the ACIP recommendations.

Does the HPV Vaccine Replace Pap Screening?

No. It is important that women continue to receive routine Pap screening. Because the HPV types targeted by the vaccine account for 70 percent of cervical cancer, the cancer risk is significantly decreased, but not eliminated.

Is HPV Testing Needed with HPV Vaccine?

No. There is no role for serologic or DNA testing for the HPV virus before or after administering the HPV vaccine. Currently, a positive result from HPV DNA testing cannot specify which among the high-risk HPV types is present. Even after infection with one type of HPV, immunization can still protect against other types covered by the vaccine.

Is this Vaccine Covered by Health Plans or Other Programs?

The Vaccines for Children (VFC) program provides the HPV vaccine for eligible girls 9 to 18 years of age. Children and adolescents up to and including 18 years of age who are either uninsured, Medi-Cal eligible, Native American, or Alaska Native are eligible for the VFC program. Eligible children and adolescents can also get VFC vaccines through federally qualified health centers or rural health centers if their private health insurance does not cover the vaccine.

By law, California's managed care plans must cover all recommended vaccines for children. Co-payments may apply for those visits. It is anticipated that most health plans will cover the vaccine but some may not cover the vaccine for adults. Please check with the specific health plan for more information.

How Can I Participate in the VFC Program?

VFC has more than 4,000 enrolled provider sites participating in California. VFC provides free routine vaccines for eligible children through age 18. Any medical practice providing vaccinations to low-income children meeting VFC eligibility may choose to become a VFC provider. To learn more about California's VFC program, including how to become a VFC provider, visit www.vfcca.org or call the VFC program office toll-free at (877) 243-8832.

Are There Patient Information Materials Available?

Fact sheets on the HPV vaccine produced by CDC can be accessed at www.hpvvaccineca.org. An interim Vaccine Information Statement, required to be given to patients, parents, or guardians, is available at www.cdc.gov/nip/publications/vis/vis-hpv.pdf.

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Additional resources can be found at:

California Department of Health Services
www.hpvvaccineca.org
Advisory Committee on Immunization Practices (ACIP)
www.cdc.gov/nip/ACIP/default.htm
American Cancer Society
www.cancer.org
American Medical Association (AMA), Sexually Transmitted Infections Vaccine Program
www.bigshouldersdubs.com/clients/AMA/vaccines04.htm
American Social Health Association, HPV Resources
www.ashastd.org/learn/learn_hpv.cfm
California Medical Association Foundation: Cervical Cancer and HPV Project
www.calmedfoundation.org/projects/HPV/index.aspx
Centers for Disease Control and Prevention, HPV Vaccine Fact Sheet
www.cdc.gov/std/hpv
Food and Drug Administration
www.fda.gov
National Cancer Institute
www.cancer.gov/cancertopics/types/cervical
National STD/HIV Prevention Training Center
www.stdhivtraining.org
Vaccine Information Statements in Multiple Languages (Immunization Action Coalition)
www.immunize.org/vis
Vaccines for Children (VFC) Program, HPV Vaccine (Resolution No. 6/06-02)
www.cdc.gov/nip/vfc/acip_resolutions/0606hpv.pdf
Vaccines for Children (VFC) Program in California
www.vfcca.org

Medical Literature

Baseman JG, Koutsky LA. The epidemiology of human papillomavirus infections. J Clin Virol. 2005;32 (Suppl 1):S16-24.

Harper DM, Franco EL, Wheeler C, et al. Efficacy of a bivalent L1 virus-like particle vaccine in prevention of infection with human papillomavirus types 16 and 18 in young women: a randomised controlled trial. Lancet. Nov 13-19 2004;364(9447):1757-1765.

Harper DM, Franco EL, Wheeler CM, et al. Sustained efficacy up to 4.5 years of a bivalent L1 virus-like particle vaccine against human papillomavirus types 16 and 18: follow-up from a randomised control trial. Lancet 2006;367 (9518):1247-1255.

Koutsky LA, Ault KA, Wheeler CM, et al. A controlled trial of a human papillomavirus type 16 vaccine. N Engl J Med. Nov 21 2002;347(21):1645-1651.

Mao C, Koutsky LA, Ault KA, et al. Efficacy of human papillomavirus-16 vaccine to prevent cervical intraepithelial neoplasia: a randomized controlled trial. Obstet Gynecol. Jan 2006;107(1):18-27.

Villa LL, Costa RL, Petta CA, et al. Prophylactic quadrivalent human papillomavirus (types 6, 11, 16, and 18) L1 virus-like particle vaccine in young women: a randomised double-blind placebo-controlled multicentre phase II efficacy trial. Lancet Oncol. May 2005;6(5):271-278.

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